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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,121	02/05/2004	Charmaine K. Harris	1023-270US02	3255

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EXAMINER
ALTER, ALYSSA MARGO

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
09/26/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/773,121	HARRIS ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-5,7-40 and 42-50* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,7-40 and 42-50* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 5/17/10, 1/7/11, 3/1/11, 3/7/11, 4/6/11 & 8/15/11.

DETAILED ACTION

BPAI Decision – Examiner Affirmed in Part

1. The BPAI rendered a decision on August 11, 2010 and upheld the decision on May 27, 2011. The Examiner's rejection of claims 38-40, 42, and 43 is affirmed and the Examiner's rejection of claims 1-5, 7-37, 44-50 is reversed.

2. The Board reversed the examiner's contentions that Mamo's dilator, which the Examiner considered to be the "sheath" is "substantially deformable" since it can be constructed from plastic. The Board concluded that "since plastics, including polyethylenes, can be manufactured to have a variety of stiffnesses, a material is not necessarily "substantially deformable" solely by virtue of being a plastic or polyethylene. See, e.g., Elizabeth Benham & Max McDaniel, Ethylene Polymers, HDPE, Encyclopedia of Polymer Science and Technology (2010), available at http ://mrw.interscience.wiley. com/emrw/9780471440260/epst/ article/pst408/current/html" (page 3). Accordingly, the rejection of independent claims 1 and 46 and dependent claims 2-5, 7-15, 44, 45, 47 and 48 was reversed.

3. Although the examiners rejection was reversed, the claims are not allowable as presented. New grounds are presented below under the modified Mamo et al. (Mamo et al. in view of DeWindt) in further view of Jacobson (US 4,545,374).

4. Additionally, the Board stated that the "Examiner never articulated how the combination of Mamo and DeWindt would have rendered obvious the step of "inserting a stimulation lead introducer to a target site within an epidural region proximate a spine of a patient via a guidewire." Since the Examiner has not mentioned this step in the

rejection, nor has the Examiner responded to Appellants' allegation that it is missing from the references, and it is not apparent in Mamo or DeWindt, we agree with Appellants that the Examiner failed to establish a prima facie case of obviousness regarding claim 16" (pages 4-5). Thus, the rejection of claim 16 and dependent claims 17-37 was reversed.

5. In light of this deficit, the Examiner has specifically indicated below how the modified Mamo et al. (Mamo et al. in view of DeWindt) meet the limitations set forth in independent claim 16 and dependents 17-37.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16-22, 24-27, 32-38, 42, and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo et al. (US Patent Publication 20020147485 A1) in view of DeWindt et al. (US 6,146,371). Mamo et al. discloses in figure 9a a flowchart of a minimally invasive method employing a dilator and a needle. The introducer of Mamo et al. includes an elongated dilator (dilator body 47 as shown in FIGS. 8a-8c) and elongated sheath (dilator sheath 49 as shown in FIGS. 8a-8c). As additionally see in figure 8a, Mamo et al. discloses a dilator having a "substantially conical distal tip".

7. Mamo et al. further discloses “The needle is adapted to be inserted posterior to the sacrum through an entry point and guided into a foramen along an insertion path to a desired location” (abstract). Since the needle is inserted through the sacrum foramen to engage with the sacral nerves (see figure 5c), the stimulation lead is delivered to a “target site within an epidural region”.

8. As depicted in the flowchart in figure 9a, in step 90 the introducer or assembled dilator (depicted in 8C with the elongated dilator 47 and elongated sheath 49) are delivered to a target site over a guide wire. The elongated dilator or dilator body is then withdrawn from the sheath (step 92) and replaced with the stimulation lead into the sheath (step 58). After the lead is inserted, then the sheath is withdrawn (step 94). Thus, since the elongated dilator and the lead are positioned within the sheath, the sheath has a “lumen sized to accommodate the dilator" and “the stimulation lead”.

9. Mamo et al. discloses the invention substantially as claimed except for the oblong cross-section. DeWindt et al. teaches “a cannula which is oval-shaped in cross section and therefore ideally suited for use in minimally invasive surgical procedures” (DeWindt et al., col. 1, lines 9-11). Since the oval shape is “ideally suited for use in minimally invasive surgical procedures” (DeWindt et al., col. 1, lines 10-11) it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the minimally invasive apparatus (the dilator, dilator sheath and needle) with the geometry (an oval cross section) as disclosed by DeWindt et al. since oval cross section “is one such modification which assists the surgeons in achieving the

goal of minimizing the wound size for a variety of surgical procedures" (DeWindt et al., col. 6, lines 3-5).

10. As to claim 17, Mamo et al. discloses a dilator with a conical distal tip and sheath as depicted in figures 8a-8c, in addition to a needle and a guide wire for application of neurostimulation therapy. "The needle is adapted to be withdrawn over the guide wire, and the dilator is adapted to be inserted over the guide wire proximal end to locate the guide wire within the dilator body lumen and to be advanced distally over the guide wire through the insertion path to dilate the insertion path to the dilator diameter" (page 2, paragraph 10). The process is displayed in figure 9a.

11. Addition, figure 9b "shows inserting and guiding a needle 36, e.g., a foramen needle 36, comprising a hollow needle body and a stylet or obdurator 40 within the needle body lumen, to the sacral nerve site in accordance with steps 50 and 52"(page 7, paragraph 98). Therefore, the needle of Mamo et al. includes a "stylet" which is withdrawn from the needle prior to the insertion of the guidewire.

12. As to claim 18, as depicted in step 94 of figure 9a, the sheath is withdrawn from the patient after the lead is inserted.

13. As to claim 19, the sacral stimulation lead stimulates the sacral nerve.

14. As to claim 20, Mamo et al. discloses on page 4, paragraph 73, the inclusion of a syringe in the implantation kits to deliver local anesthetic and "aid in implanting the stimulation lead 30". Mamo et al. does not explicitly disclose attaching a syringe to the need prior to the insertion of the guidewire so as to inject fluid into the epidural region. However, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to employ the syringe to deliver the fluid to the epidural region in order to provide the patient with "local anesthetic" prior to the implantation of the medical lead into the epidural region (i.e. an epidural anesthesia).

15. As to claims 21-22 and 36, “The dilator body 47 is preferably conductive, and the dilator sheath 49 is preferably non-conductive but may bear radiopaque and visually observable depth marks 51 along its length to facilitate radiographic imaging when it is extended into the patient's body” (page 6, paragraph 91). Therefore, Mamo et al. “fluoroscopic imaging” and "imaging technique".

16. As to claims 24, 26-27, 33 and 42, the modified Mamo et al. discloses a dilator, dilator sheath and needle with an oval cross section (see above).

17. As to claims 25, 34-35, 37 and 43, the modified Mamo et al. discloses the claimed invention except for the specific values of the width and height of the sheath and dilator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the sheath and dilator, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05). Furthermore, such a modification would provide the predictable results of modifying the stimulation device to meet specific patient therapeutic needs and requirements.

18. As to claim 32, Mamo et al. depicts in figure 8c, the dilator 47 is longer than the sheath 49, and thus “at least as long as the sheath”.

19. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mamo et al., as applied to claims 16-22, 24-27, 32-38, 42, and 43 above, in further view of Otten (US 5,255, 691). The modified Mamo et al. discloses the claimed invention except for the Tuohy needle. Otten teaches that it is known to utilize a Tuohy, for the purpose of accessing the epidural space of the spinal column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the needle as taught by the modified Mamo et al. with the Tuohy needle as taught by Otten, since it was known in the art to utilize Tuohy needles for introducing a guide wire or stylet into the body.

20. Claims 1-5, 7-15 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mamo et al., as applied to 16-22, 24-27, 32-38, 42, and 43 above, in further view of Jacobson (US 4,545,374). The modified Mamo et al. discloses the device substantially as claimed but does not explicitly disclose that the dilator “sheath material" is “substantially deformable”. While Mamo et al. does disclose that “the dilators 42 can be metal or plastic” (page 4, paragraph 74), Mamo et al. does not explicitly state that the plastic “is substantially deformable". Jacobson discloses “cannula 11 may be constructed of metal or of any material compatible with general surgical sterility and mechanical requirements as described herein. It is preferably constructed of flexible, resilient material in order to accommodate minute bends or stresses caused by the surgeon as he manipulates instruments in the cannula. If the cannula is not flexible, inability to flex it will tend to limit the desired operating area. Cannula flexibility allows it to adjust to slight movements of the surgeon and tends to

keep the inserted cannula end next to the chosen operating area on the disc regardless of the movement at the other end" (col. 6, lines 14-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made construct the plastic dilator (elongated dilator and sheath; see figure 8c) with flexible or substantially deformable plastic as disclosed by Jacobson in order to provide the predictable results of accommodating "minute bends or stresses caused by the surgeon" during the implantation of the lead, as well as allowing the surgeon the flexibility to work within the desired operative area.

21. As to claims 7, 9, 29 and 31, the modified Mamo et al. discloses the device substantially as claimed with a substantially deformable plastic but does not explicitly disclose the plastic is polyethylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plastic material used, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07) Furthermore, according to Columbia University Press Dictionary, polyethylene is a "widely used plastic".

22. Claims 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mamo et al., as applied to 1-5, 7-15 and 44-45 above, in further view of Redko et al. (US 6,309,401 B1). The modified Mamo et al. discloses the inventions substantially as claimed but does not specifically disclose a stimulation lead with an oblong cross-section. However, leads with oblong cross-sections, such as paddle-

shaped leads, are well known in the art. Redko et al. disclose in col. 1, lines 28-32, "Surgically implantable paddle style leads, or flat leads, and percutaneous insertable wire leads for the spinal canal have been in use for some time. These paddle style, or flat leads, and wire leads are used for electrical stimulation of neurons in the spinal canal". Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation lead of the modified Mamo et al. to be a paddle-style lead (and thus a lead with an oblong cross-section) since such leads are well know to stimulate the spinal canal. Furthermore, such a modification provides the predictable results of increasing the electrode surface area while still maintaining a low-profile structure.

23. As to claims 49-50, the modified Mamo et al. discloses the claimed invention except for the specific values of the width and height of the sheath and lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the sheath and lead, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05). Furthermore, such a modification would provide the predictable results of modifying the stimulation device to meet specific patient therapeutic needs and requirements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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